5

10

Express Mail No. EV339203254US Date of Deposit: September 25, 2003

## **CLAIMS**

1. A method of bowel care, comprising:

chronically administering a therapeutically effective amount of a drug combination comprising an acetylcholinesterase inhibitor and an anti-cholinergic agent to a subject having chronic intestinal pseudo-obstruction.

- 2. The method of claim 1, wherein the acetylcholinesterase inhibitor is neostigmine, physostigmine, ambenonium, pyridostigmine, edrophonium, demecarium, echothiophate, or pralidoxime.
- 3. The method of claim 2, wherein the acetylcholinesterase inhibitor is neostigmine.
- The method of claim 1, wherein the anti-cholinergic agent is
  glycopyrrolate, atropine, methscopolamine, homatropine, methantheline, propantheline, anisotropine, clidinium, hexocyclium, isopropamide, mepenzolate, oxyphenonium, or tridihexethyl.
- 5. The method of claim 4, wherein the anti-cholinergic agent is glycopyrrolate.
  - 6. The method of claim 1, wherein the acetylcholinesterase inhibitor is neostigmine and the anti-cholinergic agent is glycopyrrolate.
- 7. The method of claim 6, wherein the therapeutically effective amount of the drug combination is about 1 mg to about 2 mg neostigmine and about 0.2 mg to about 0.4 mg glycopyrrolate.

10

20

- 8. The method of claim 6, wherein the therapeutically effective amount of the drug combination is a ratio of neostigmine to glycopyrrolate of about 2.5:1 to about 10:1 by weight.
- 5 9. The method of claim 8, wherein the therapeutically effective amount of the drug combination is a ratio of neostigmine to glycopyrrolate of about 5:1 by weight.
  - 10. The method of claim 1, wherein the chronic intestinal pseudo-obstruction is an effect of spinal cord injury, amyotrophic lateral sclerosis, spina bifida, multiple sclerosis, Parkinson's disease or dementia.
  - 11. The method of claim 10, wherein the chronic intestinal pseudo-obstruction is an effect of spinal cord injury.
- 15 12. The method of claim 11, wherein the chronic intestinal pseudo-obstruction is an effect of paraplegia or quadriplegia.
  - 13. The method of claim 1, wherein the acetylcholinesterase inhibitor and the anti-cholinergic agent are administered at about the same time.
  - 14. The method of claim1, wherein the anti-cholinergic agent is administered about 1 to about 10 minutes after the acetylcholinesterase inhibitor.
- 15. The method of claim 1, wherein the method of administration of the acetylcholinesterase inhibitor is intramuscular injection, intravenous injection, rectal suppository, transnasal spray, sublingual tablets, or sublingual drops.

Express Mail No. EV339203254US Date of Deposit: September 25, 2003

- 16. The method of claim 1, wherein the method of administration of the anti-cholinergic agent is intramuscular injection, intravenous injection, rectal suppository, transnasal spray, sublingual tablets, or sublingual drops.
- 5 17. The method of claim 1, wherein the acetylcholinesterase inhibitor and the anti-cholinergic agent are administered by the same method of administration.
  - 18. The method of claim 17, wherein the method of administration is intramuscular injection, intravenous injection, rectal suppository, transnasal spray, sublingual tablets, or sublingual drops.
  - 19. The method of claim 18, wherein the method of administration is intramuscular injection or intravenous injection.
- 15 20. The method of claim 1, wherein the chronic administration occurs at least one time per week over a period of at least one month.
  - 21. The method of claim 20, wherein the chronic administration occurs over a period of at least six months.

20

10

- 22. The method of claim 1, wherein the chronic administration occurs at least three times per week over a period of at least one month.
  - 23. A method of bowel care for a subject comprising:
- 25 identifying a subject having chronic intestinal pseudo-obstruction as an effect of spinal cord injury; and

co-administering to the subject a therapeutically effective amount of a drug combination comprising about 1 mg to about 2 mg of neostigmine and about 0.2 mg to about 0.4 mg glycopyrrolate.

10

20

- 24. The method of claim 23, wherein the drug combination is chronically co-administered at least one time per week for at least one month.
- 5 25. The method of claim 24, wherein the drug combination is chronically co-administered at least three times per week.
  - 26. The method of claim 24, wherein the drug combination is chronically co-administered for at least six months.
  - 27. A pharmaceutical composition comprising a therapeutically effective amount of a drug combination comprising neostigmine and glycopyrrolate in a weight ratio of neostigmine to glycopyrrolate of about 2.5:1 to about 10:1.
- 15 28. The pharmaceutical composition of claim 27, wherein the weight ratio of neostigmine to glycopyrrolate about 5:1.
  - 29, The pharmaceutical composition of claim 27, comprising about 1 mg to about 2 mg neostigmine and about 0.2 mg to about 0.4 mg glycopyrrolate.
  - The pharmaceutical composition of claim 27, comprising about 2 mg neostigmine and about 0.4 mg glycopyrrolate.
- 31. The pharmaceutical composition of claim 27, wherein the composition is in the form of a rectal suppository.